

S. AMY

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/530,375	ORMEROD ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Konata M. George	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTO-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1.  This communication is responsive to Response to Office action dated January 5, 2004.
2.  The allowed claim(s) is/are 24,25,28-31 and 37-51.
3.  The drawings filed on 07 July 2000 are accepted by the Examiner.
4.  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a)  All    b)  Some\*    c)  None    of the:
    1.  Certified copies of the priority documents have been received.
    2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3.  Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5.  A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6.  CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a)  including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1)  hereto or 2)  to Paper No./Mail Date \_\_\_\_\_.
  - (b)  including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7.  DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

#### Attachment(s)

1.  Notice of References Cited (PTO-892)
2.  Notice of Draftsperson's Patent Drawing Review (PTO-948)
3.  Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4.  Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5.  Notice of Informal Patent Application (PTO-152)
6.  Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_.
7.  Examiner's Amendment/Comment
8.  Examiner's Statement of Reasons for Allowance
9.  Other \_\_\_\_\_.

## **DETAILED ACTION**

Claims 24, 25, 28-31 and 37-51 are pending in this application.

### ***Action Summary***

1. Examiner acknowledges the cancellation of claims 32-36. Therefore, any and all rejections directed towards those claims are hereby withdrawn. Examiner also acknowledges the addition of claims 40-51.
2. The rejection of claims 24, 25, 28 and 29 under 35 U.S.C. 102(b) as being anticipated by Francoeur et al. is hereby withdrawn.
3. The rejection of claims 24, 25, 28, 29, 37 and 38 under 35 U.S.C. 102(b) as being anticipated by Pittrof et al. is hereby withdrawn.
4. The rejection of claims 24, 25, 28-31 and 36-39 under 35 U.S.C. 103(a) over Pitroff et al. in view of San-Doz, LTD. is hereby withdrawn.

### ***Statement of Reasons for Allowance***

5. The following is an examiner's statement of reasons for allowance:

The claims are allowable over the cited prior art because the prior art does not teach, disclose nor make obvious a topical formulation for the treatment of dermatological conditions which comprises a macrocyclic lactone antibiotic and a permeation modulator which are present in relative amounts such that when a therapeutic amount is applied to the skin a minimal systemic effect is produced. The closest prior art of Francoeur discloses a topical formulation comprising the same two ingredients,

however, the formulation is delivered systemically to remote regions in the body.

Examiner acknowledges FK506 or SDZ ASM 981 of claim 1 are generic terms for examples of immunosuppressive macrolides.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

### ***Conclusion***

6. Claims 24, 25, 28-31 and 37-51 are allowed.

### ***Telephone Inquiries***

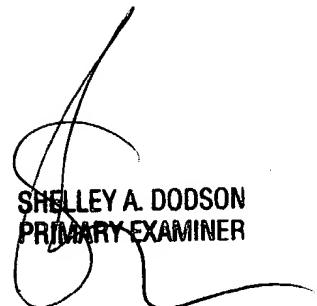
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is (571) 272-0613. The examiner can normally be reached from 8AM to 5:30PM Monday to Thursday, and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached at (571) 272-0602. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and for After Final communications.

Art Unit: 1616

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Konata M. George



SHELLEY A. DODSON  
PRIMARY EXAMINER